PROMEPLA

Material Certificate

Material Code M0636 **Revision** 00

Type	PP
Brand name	100-GB06
Supplier	INEOS

Sterilization Stablity:

	Compliant	Comments
Ethylene Oxyde	YES	-

Biocompatibility Data:

	Compliant	Standard	Comments
USP Class VI	YES	USP	US Pharmacopoeia 29, <88>

Main Regulatory Compliances:

	Compliant	Comments
BPA	YES	Not used in the manufacturing process
CONEG (Cadmium, chromium, lead and mercury)	YES	Not used in the manufacturing process
Food Contact	YES	Annex IV, Regulation (EU) 10/2011/ FDA 21 CFR 177.1520 and 21 CFR 170-189
European Directive (2004/12/EC) Packaging and Packaging Waste	YES	-
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
European Directive 2012/19/UE - WEEE	YES	-
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	<1 ppm
TSE / BSE	YES	no risk manufactured from starting substances or contain additives which may be of genetically modified organism's origin.
US Pharmacopoeia	YES	
European Directive (EC 1907/2006) REACH	YES	-
MSDS	YES	-

Technical Characteristics:

	Value	Measuring Method	Comments
Extrusion	YES	-	-
Injection	YES	-	-
Density	<1	-	-
Color	off-white	-	-
Melt Flow Rate	6 g/ 10min	ISO 1133-1	230°C/ 2.16 kg
Modulus of Elasticity / Young modulus	1450 MPa	ISO 178	-
Tensile Strength at Yield	34 MPa	ISO 527-1/ -2	-

R&D Validation	FRA	**QA/RA Validation**	CGI
Date	25-08-2017	**Date**	13-09-2017